22 January 2019
EMA/CVMP/805493/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the December 2018 meeting

Chair: D. Murphy – Vice-chair: H. Jukes

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of one item under agenda point 7.2.

ii. CVMP delegates' list of intended participation and identified interests

The attendance list was completed and competing interests were identified for the December 2018 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

iii. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

iv. Adoption of the minutes of the previous meeting

The minutes of the November 2018 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- The Committee discussed the rapporteurs' joint assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs in horses for a substance (EMEA/V/MRL/005010/FULL/0001), and adopted a list of outstanding issues to be addressed in writing. The adoption of the opinion is foreseen for the February 2019 meeting of the Committee.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the generic product **Kriptazen** (EMEA/V/C/004868/0000), recommending the granting of a marketing authorisation. The product is a new antiprotozoal product for the prevention and reduction of diarrhoea in newborn calves due to *Cryptosporidium parvum*. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **EVANT** (EMEA/V/C/004902/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for active immunisation of chicks from 1 day of age against coccidiosis. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Zulvac BTV** (formerly Zulvac BTV Ovis) (EMEA/V/C/004185/X/0001), a multi-strain vaccine, recommending the extension of the marketing authorisation to add a new food-producing target animal

species (cattle). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new vaccine (EMEA/V/C/004858/0000). The Committee agreed that an oral explanation would not be requested, and noted the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview including the list of questions, and agreed comments on the draft product information for a new product for dogs (EMEA/V/C/004735/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of questions, and agreed comments on the draft product information for a new antiparasitic product for dogs (EMEA/V/C/004846/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of questions, and agreed comments on the draft product information for a new antiparasitic product for dogs (EMEA/V/C/004846/0000). The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee endorsed the list of the ad hoc expert group members to support the Committee for the re-examination of the negative CVMP opinion adopted for **HorStem** (EMEA/V/C/004265/0000), a stem-cell based veterinary product intended for the treatment of osteoarthritis in horses.

2.5 Other issues

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **GALLIPRANT** (EMEA/V/C/004222/II/0001), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Aivlosin** (EMEA/V/C/000083/II/0072), recommending the variation of the marketing authorisation to implement changes to the SPC warnings. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **Aivlosin** (EMEA/V/C/000083/II/0074/G), recommending the variation of the marketing

authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **BRAVECTO** (EMEA/V/C/002526/II/0030/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **BRAVECTO PLUS** (EMEA/V/C/002526/II/0002/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, and the rapporteur's assessment report for a type II grouped variation for **OSURNIA** (EMEA/V/C/003753/II/0009/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II grouped variation for **HALAGON** (EMEA/V/C/004201/II/0002/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II grouped variation (subject to a worksharing procedure) for **Canigen L4** and **Nobivac L4** (EMEA/V/C/xxxx/WS1439/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **Ecoporc SHIGA**, **RESPIPORC FLU3**, **RESPIPORC FLUpan H1N1** and **NAP** (EMEA/V/C/xxxxxx/WS1484), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a CVMP list of outstanding issues for a type II variation for **ClomicaIm** (EMEA/V/C/000039/II/0027), concerning quality changes.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Vectra 3D** (EMEA/V/C/002555/II/0011) to change the legal status.
- The Committee adopted a list of questions for a type II variation for **COLIPROTEC F4/F18** (EMEA/V/C/004225/II/0005) to add a new therapeutic indication.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- There were no items for discussion.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- The Committee endorsed the letter to EDQM considering the recommendations made by CHMP and CVMP under Art. 5(3) and Art. 30(3) of Regulation (EC) No. 726/2004, respectively, regarding human medicinal products for parenteral administration and veterinary medicinal products for parenteral administration to horses, containing gentamicin adopted at the November 2019 meeting.

4.7 Other issues

- There were no items for discussion.

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- There were no items for discussion.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 09.11.2018 – 06.12.2018:

Product	Period
Bovilis Blue-8 (EMEA/V/C/004776)	21.11.2017 – 20.11.2018
Broadline (EMEA/V/C/002700)	04.12.2017 – 03.12.2018

Product	Period
Contacera (EMEA/V/C/002612)	06.12.2017 – 05.12.2018
DRAXXIN (EMEA/V/C/000077)	11.11.2017 – 10.11.2018
Easotic (EMEA/V/C/000140)	20.11.2017 – 19.11.2018
Equip WNV (EMEA/V/C/000137)	21.11.2017 – 20.11.2018
Masivet (EMEA/V/C/000128)	17.11.2017 – 16.11.2018
Meloxoral (EMEA/V/C/000151)	19.11.2017 – 18.11.2018
Oxyglobin (EMEA/V/C/000045)	29.11.2017 – 28.11.2018
Porcilis AR-T DF (EMEA/V/C/000055)	16.11.2017 – 15.11.2018
Quadrisol (EMEA/V/C/000032)	04.12.2017 – 03.12.2018
Rabitec (EMEA/V/C/004387)	01.12.2017 – 30.11.2018
Stronghold (EMEA/V/C/000050)	25.11.2017 – 24.11.2018
Vectra 3D (EMEA/V/C/002555)	04.12.2017 – 03.12.2018

5.4 Renewals

- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Fungitraxx** (EMEA/V/C/002722/R0004).
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Vectra Felis** (EMEA/V/C/002746/R/0008), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Equisolon** (EMEA/V/C/002526/R/0004), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the final CVMP opinion, the final CVMP assessment report and the product information for the renewal of the marketing authorisation for **Bravecto** (EMEA/V/C/002526/R/0028) further to the re-examination of the opinion adopted during the Committee meeting held on 9-11 October 2018. The Committee, having assessed the marketing authorisation holder's grounds for re-examination, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation. Based on pharmacovigilance grounds, the Committee concluded that a further 5-year renewal was necessary. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.06.2017 – 31.05.2018 for **APOQUEL** (EMEA/V/C002688) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.18-31.07.18 for **Credelio** (EMEA/V/C004247) with a recommendation to amend the product information.
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Coliprotec F4-F18 (EMEA/V/C/004225)	01.02.18-31.07.18
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	01.08.15-31.07.18
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	01.08.15-31.07.18
Profender (EMEA/V/C/000097)	01.08.15-31.07.18
Reconcile (EMEA/V/C/000133)	01.08.15-31.07.18
Vectra 3D (EMEA/V/C/002555)	01.07.17-30.06.18
VEPURED (EMEA/V/C/004364)	01.03.18-31.08.18
Versican Plus L4 (EMEA/V/C003680)	01.08.17-31.07.18
Versican Plus Pi L4 (EMEA/V/C003683)	01.08.17-31.07.18
Versican Plus Pi L4 R (EMEA/V/C003682)	01.06.17-31.05.18
ZACTRAN (EMEA/V/C000129)	01.02.18-31.07.18

- The Committee endorsed the list of products and calendar for signal detection analysis.

5.6 Supervision and sanctions

Information relating to supervision and sanctions will not be published as it would be undermining the purpose of such inspections.

The following document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee agreed that no EU comments were needed on the updated draft VICH GL57 on marker residue depletion studies to establish product withdrawal periods in aquatic species (EMA/CVMP/VICH/517152/2013), which had been amended in response to comments received during the public consultation.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- There were no items for discussion.

The following document was circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 at this meeting cannot be released at the present time as it is deemed to be confidential.

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP-V procedures cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 4 December 2018, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted the revised guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/EWP/016/2000-Rev.3) and the overview of comments (EMA/CVMP/EWP/755602/2017) received during the public consultation. The revised guideline will come into effect in July 2019. – *see also 7 5.*

- The Committee adopted a new guideline on the sterilisation of the medicinal product, active substance, excipient and primary container (EMA/CHMP/CVMP/QWP/850374/2015) and the overview of comments (EMA/CHMP/CVMP/QWP/366428/2018) received during the public consultation. The new guideline will come into effect in July 2019.

7.3 Safety Working Party (SWP-V)

- The Committee adopted the revised guideline (EMA/CVMP/SWP/66781/2005-Rev.2) on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market for release for public consultation until the end of August 2019.

- The Committee adopted a new guideline (EMA/CVMP/SWP/377245/2016) on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products and the overview of comments (EMA/CVMP/SWP/610519/2017) received during the public consultation. As processes will need to be established by applicants to comply with requirements of the guideline, the CVMP agreed to an implementation period of 18 months. Accordingly, the new guideline will come into effect in July 2020.

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the revised guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/EWP/016/2000-Rev.3) and the overview of comments (EMA/CVMP/EWP/755602/2017) received during the public consultation. The revised guideline will come into effect in July 2019. – *see also 7 2.*

- The Committee adopted a draft guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances (EMA/CVMP/EWP/755916/2016), for release for public consultation until the end of August 2019. This guideline will replace the current NtA guideline on anticoccidials used for the therapy of coccidiosis in chickens, turkeys and geese (7AE15a), which was adopted prior to 1995.
- The Committee adopted new questions and answers on the CVMP guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees (EMA/CVMP/EWP/459883/2008).

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted the revised AWP mandate (EMA/CVMP/AWP/749774/2012-Rev.4).
- The Committee discussed the overview of comments received during the second public consultation on the "Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals" (EMA/CVMP/AWP/706442/2013), and agreed that the AWP will proceed with the revision of the guideline once AWP activities resume next year.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the revised guideline (EMA/CVMP/IWP/105506/2007-Rev.1) on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza, Bluetongue and Foot-and-Mouth disease and overview of comments received (EMA/CVMP/IWP/235788/2018) during the public consultation. The Committee also adopted revised questions and answers on the above-mentioned revised CVMP guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza, Bluetongue and Foot-and-Mouth disease. The revised guideline will come into effect in July 2019.
- The Committee adopted a draft revised guideline (EMA/CVMP/IWP/170689/2016-Rev.1) on production and control of allergen products for use in animals, for release for public consultation until the end of August 2019.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 20-21 November 2018, and noted the agenda of the meeting.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

7.10 Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

- There were no items for discussion.

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following document was circulated for information:

- Minutes of the SAWP-V meeting held on 6 November 2018.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee adopted the draft scientific advice by the Antimicrobial Advice Ad Hoc Expert Group on the preliminary risk profiling for new antimicrobials (EMA/682199/2017) in the context of the European Commission request for an update of the previous scientific advice on the impact on public health and animal health of the use of antibiotics in animals (EMA/381884/2014). The purpose of the adopted risk profiling is to provide advice on potential antimicrobial resistance public health risks at an early stage in the development of antimicrobial veterinary medicines. The advice will be submitted to the CHMP for adoption and subsequent publication for consultation until 31 March 2019.
- The Committee discussed the draft scientific advice by the Antimicrobial Advice Ad Hoc Expert Group on the categorisation of antimicrobials, including written comments received from CVMP members. The secretariat advised the committee that there would also be a discussion on the document at CHMP (meeting of 10-13th December) and that certain concerns had been raised in that forum relating to the categorisation of certain antimicrobial (sub-)classes. A document detailing these specific concerns was not available for the CVMP to consider. It is foreseen that the AMEG categorisation advice will be adopted at the January 2019 meeting for release for consultation. All CVMP members were invited to review the document and provide any further comments in writing within one week.
- The Committee discussed further activities and timelines in relation to the draft CVMP reflection paper on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation. In line with BCP Phase 4, work on finalisation of the reflection paper would be postponed until the end (second half) of 2019.

8.4 Pharmacovigilance

- There were no items for discussion.

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to contain commercially confidential information.

- The Committee endorsed the public statement on the evaluation of the compliance of marketing authorisation holders with the CVMP Risk Management Strategy with respect to the potential presence of replication competent endogenous retrovirus RD114 in starting materials and final products of feline and canine vaccines (EMA/CVMP/814776/2018).

The following document was circulated for information:

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for Community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee agreed to the transfer of all (co-)rapporteurships and peer reviewer responsibilities from N. Garcia del Blanco to R. Cooney.
- The Committee agreed to the transfer of (co-)rapporteurships and peer reviewer responsibilities from P. Hekman to J. Poot.
- The Committee agreed to the transfer of all peer reviewer responsibilities from J. P. Duarte da Silva to M. Azevedo Mendes.

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential.

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- The Committee noted the draft minutes of the meeting held on 8-9 November 2018 and the agenda of the meeting held on 6-7 December 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the CVMP work plan for 2019 (EMA/CVMP/302436/2018).
- The Committee endorsed the minutes and recommendations relating to ‘end-heavy’ procedures raised in the informal presidency meeting held on 25-26 October 2018 in Helsinki, Finland.
- The Committee endorsed the revised guidance on ‘Appointment and responsibilities of the rapporteur and co-rapporteur for procedures regarding veterinary medicinal products’ (EMA/CVMP/468877/2009-Rev.1).
- The Committee re-appointed K. Baptiste as a co-opted member to complement its expertise in antimicrobial resistance for a further 3-year mandate. The Committee also appointed R. Carapeto García as a co-opted member to complement its expertise in environmental risk assessment for a 3-year mandate.
- The Committee endorsed the training priorities for 2019.
- The Committee received an update on the European Medicines Agency relocation.
- The Committee received an update on EudraVigilance Veterinary 3 project.
- The Committee noted the invitation to the CVMP/CMDv presidency meeting to be held in May 2019 in Hungary, under the Romanian presidency.

- The Committee noted the workshop on the advancing regulatory science to 2025 for veterinary medicines, held on 6 December 2018 at the European Medicines Agency premises in London and noted the agenda (link).

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the December 2018 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the December 2018 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
AT	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
CY	Alia Michaelidou-Patsia	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• **2.3** one item • **5.5** Profender
PT	Maria Azevedo Mendes	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
BG	Svetoslav Branchev	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
EL	Angeliki Tsigouri	Full involvement	
FR	Sylvie Louet	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
SI	Maja Turk	Full involvement	
UK	Rory Cooney	Full involvement	
NO	Tonje Høy	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were only evaluated against the topics they have been invited to talk about.			
AT	Barbara Zemann - *remotely*	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Christine Schwarz - *remotely*	Full involvement	
DE	Nikola Lange - *remotely*	Full involvement	
DE	Kathrin Schmidt - *remotely*	Full involvement	
DE	Svenja Sander - *remotely*	Full involvement	
DE	Sarah Bolda - *remotely*	Full involvement	
DK	Nanna Aaby Kruse	Full involvement	
DK	Niels Christian Kyvsgaard - *remotely*	Full involvement	
ES	Pablo García Cambero - *remotely*	Full involvement	
ES	Rosa Donoso Carrero- *remotely*	Full involvement	
ES	Luis Agote Casado - *remotely*	Full involvement	
ES	Aránzazu González-Canga - *remotely*	Full involvement	
FI	Pertti Pellinen - *remotely*	Full involvement	
FI	Tiina Hakonen - *remotely*	Full involvement	
FI	Jukka Pakkanen - *remotely*	Full involvement	
FI	Martti Nevalainen - *remotely*	Full involvement	
FI	Jonna Kumpulainen - *remotely*	Full involvement	
FR	Florence Pillet - *remotely*	Full involvement	
FR	Meg-Anne Moriceau - *remotely*	Full involvement	
FR	Nathalie Bridoux - *remotely*	Full involvement	
SE	Mats Welin	Full involvement	
SE	Catarina Eriksson - *remotely*	Full involvement	
SE	Jennie Sandberg - *remotely*	Full involvement	
SE	Malin Öhlund - *remotely*	Full involvement	
UK	Sharon Reynolds		
UK	Sam Fletcher - *remotely*		
UK	John Mitchell - *remotely*		
UK	Stephen Spencer - *remotely*		

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Laetitia Le Letty
ERAWP	Jason Weeks
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	Ellen-Margrethe Vestergaard
PhVWP-V	Els Dewaele - *remotely*
QWP	---
SAWP-V	Rory Breathnach
SWP-V	---

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

European Medicines Agency support
Meeting run with relevant support from the EMA staff